



argenx reports full year 2019 financial results and provides fourth quarter business update

- ▮ Topline data from Phase 3 ADAPT trial of efgartigimod in gMG expected in mid-2020
- ▮ Continued progress across broadest FcRn antagonist pipeline with up to five Phase 3 trials to be ongoing in 2020
- ▮ Ended 2019 well-capitalized to advance late-stage pipeline with €1.3 billion in cash, cash equivalents and current financial assets

February 27, 2020

Breda, the Netherlands / Ghent, Belgium – argenx (Euronext & Nasdaq: ARGX), a clinical-stage biotechnology company developing a deep pipeline of differentiated antibody-based therapies for the treatment of severe autoimmune diseases and cancer, today announced its financial results for the full year 2019 and provided a fourth quarter business update and outlook for 2020.

“The significant achievements we made throughout 2019 have provided the foundation for us to execute yet another exciting year ahead as we advance our ‘argenx 2021’ vision to become a global, integrated immunology company,” commented Tim Van Hauwermeiren, CEO of argenx. “We are progressing our entire FcRn pipeline across four indications with a fifth to be announced this year and are planning for a 2021 launch of efgartigimod in gMG, which could be the first approved FcRn antagonist.”

“We continue to build innovation into every step of our development, highlighted by our collaborative Innovative Access Program translating immunology breakthroughs into medicines, our unique trial designs incorporating input from our patients, and our integrated commercial thinking with the launch of the first real-world evidence study in MG. We have demonstrated our ability to perform across our late-stage pipeline and will prioritize maintaining this reputation for execution in 2020 with up to five registrational trials to be ongoing.”

FOURTH QUARTER 2019 AND RECENT HIGHLIGHTS

argenx continues to execute on its “argenx 2021” vision to become a fully integrated, global immunology company, which includes the building of two initial commercial franchises in neuromuscular disorders and hematology/oncology and the expanding of its global presence to support its anticipated first commercial launch of efgartigimod in 2021.

Efgartigimod: First-in-class opportunity across range of high-value autoimmune indications

Efgartigimod is a human IgG1 Fc fragment engineered for optimal blocking of FcRn and targeted reduction of IgG autoantibodies. argenx expects to have up to five registrational trials ongoing in 2020. Efgartigimod is currently being evaluated in four targeted indications where IgG autoantibodies are directly pathogenic, including:

- ▮ Generalized Myasthenia Gravis (gMG)
 - ▮ Completed enrollment of 167 patients in global, multi-center Phase 3 ADAPT trial with 10mg/kg intravenous (IV) efgartigimod. Topline results from ADAPT expected in mid-2020
 - ▮ Received Fast Track designation for efgartigimod in MG from U.S. Food and Drug Administration (FDA)
 - ▮ Biologics License Agreement (BLA) expected to be filed in fourth quarter of 2020 with launch planned for 2021
 - ▮ Plans to engage with FDA in 2020 on potential bridging strategy for 1000mg subcutaneous (SC) ENHANZE®-efgartigimod
- ▮ Primary Immune Thrombocytopenia (ITP)
 - ▮ Global Phase 3 registrational program includes:
 - ▮ Ongoing Phase 3 ADVANCE trial evaluating approximately 150 primary ITP patients dosed with 10mg/kg IV efgartigimod for both induction and maintenance of platelet response
 - ▮ ADVANCE SC trial expected to initiate in second half of 2020 evaluating 10mg/kg IV efgartigimod for induction of platelet response and fixed dose of SC efgartigimod for maintenance
 - ▮ Small confirmatory IV trial expected to initiate in first half of 2020
 - ▮ Presented previously announced data from completed Phase 2 proof-of-concept trial in December 2019 at 61st American Society of Hematology (ASH) Annual Meeting demonstrating that efgartigimod was well-tolerated and showed correlation of reduced IgG levels, increased platelet counts and reduced bleeding in ITP patients
 - ▮ Published Phase 2 data in American Journal of Hematology in article titled, “Phase 2 study of efgartigimod, a novel FcRn antagonist, in adult patients with primary immune thrombocytopenia”
- ▮ Pemphigus Vulgaris (PV)
 - ▮ Announced positive proof-of-concept data in 23 patients from Phase 2 trial evaluating 10mg/kg and 25mg/kg IV efgartigimod, which support advancement to registrational trial anticipated to start in second half of 2020
 - ▮ 78% (18/23) of patients achieved rapid disease control (DC); median time to DC for both monotherapy and combination therapy is 14-15 days
 - ▮ Fast complete clinical remission (CR) observed within 2-10 weeks of treatment in 70% (5/7) of patients receiving optimized dosing regimen
 - ▮ Established optimized dosing regimen to be weekly or bi-weekly dosing of efgartigimod in combination with oral prednisone (0.25-0.5mg/kg)
 - ▮ Patients still in trial in extended dosing cohort; detailed results of Phase 2 data to be presented during Society for Investigative Dermatology Annual Meeting in May 2020
- ▮ Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
 - ▮ Launched Phase 2 ADHERE trial with SC ENHANZE®-efgartigimod
- ▮ Fifth efgartigimod indication expected to be announced in 2020

argenx has established proof-of-concept in all three beachhead indications in neuromuscular disorders, hematology and dermatology therapeutic areas for efgartigimod.

Cusatuzumab: First-in-class opportunity with potential in hematological malignancies

Cusatuzumab is an anti-CD70 monoclonal antibody being developed under an exclusive global collaboration and license agreement with Janssen for the treatment of acute myeloid leukemia (AML), high-risk myelodysplastic syndromes (MDS) and other hematological malignancies.

- ┆ Enrollment ongoing in dose-confirming Phase 2 pivotal CULMINATE trial of cusatuzumab in combination with azacitidine for newly diagnosed, elderly AML patients who are unfit for intensive chemotherapy
- ┆ Phase 1b platform trial underway in various AML subpopulations and settings with initial trial evaluating combinations of cusatuzumab, venetoclax and azacitidine; additional trials expected to launch under platform trial in first half of 2020
- ┆ Randomized Phase 2 trial of cusatuzumab in combination with azacitidine in higher-risk MDS patients expected to launch in first half of 2020
- ┆ Phase 1 trial of cusatuzumab in combination with azacitidine to launch in first half 2020 in Japanese patients with AML and MDS
- ┆ Data update from cusatuzumab development expected in 2020

ARGX-117: First-in-class anti-C2 antibody expected to enter clinic in first quarter 2020

ARGX-117 is a complement-targeting antibody against C2 with potential therapeutic applications in multiple autoimmune diseases.

- ┆ Phase 1 trial in healthy volunteers expected to begin in first quarter of 2020
 - ┆ Multiple doses and formulations (IV and SC ENHANZE®-efgartigimod) to be evaluated as part of dose-finding work
 - ┆ Following analysis of Phase 1 data in fourth quarter of 2020, argenx plans to launch Phase 2 proof-of-concept trial in multifocal motor neuropathy (MMN) within its neuromuscular franchise and to develop in additional indications

Early-stage Pipeline

argenx continues to expand its early-stage pipeline with first-in-class antibodies against immunologic targets:

- ┆ Lead optimization work ongoing of ARGX-118 for airway inflammation
- ┆ New product candidate ARGX-119 expected to be announced in 2020

Collaborations

- ┆ Received first development milestone payment under Janssen collaboration for achievement of enrollment milestone in Phase 2 pivotal CULMINATE trial
- ┆ Awarded first clinical milestone payment under AbbVie collaboration for initiating first-in-human clinical trial with antibody product ABBV-151 (formerly named ARGX-115), which was created as part of argenx's Innovative Access Program and exclusively licensed to AbbVie in 2016

YEAR 2019 FINANCIAL RESULTS (CONSOLIDATED)

in thousands of €	Year Ended December 31,		
	2019	2018	Variance
Revenue	€ 69,783	€ 21,482	€ 48,301
Other operating income	€ 12,801	€ 7,749	€ 5,052
Total operating income	€ 82,584	€ 29,231	€ 53,353
Research and development expenses	€ (197,665)	€ (83,609)	€ (114,056)
Selling, general and administrative expenses	€ (64,569)	€ (27,471)	€ (37,098)
Changes in fair value on financial assets	1,096	—	1,096
Operating loss	€ (178,554)	€ (81,849)	€ (96,705)
Financial income	€ 14,399	€ 3,694	€ 10,705
Financial expense	€ (124)	€ —	€ (124)
Exchange gain/(losses)	€ 6,066	€ 12,308	€ (6,242)
Loss before taxes	€ (158,213)	€ (65,847)	€ (92,366)
Income tax expense	€ (4,752)	€ (794)	€ (3,958)
Loss for the year and total comprehensive loss	€ (162,965)	€ (66,641)	€ (96,324)
Net increase in cash, cash equivalents and current financial assets compared to year-end 2018 and 2017	€ 771,252	€ 204,795	

DETAILS OF THE FINANCIAL RESULTS

Cash, cash equivalents and current financial assets totaled €1,335.8 million for the year ended December 31, 2019, compared to €564.6 million for the year ended December 31, 2018. The increase in the year-end cash balance on December 31, 2019 resulted primarily from (i) the closing of the collaboration and license agreement for cusatuzumab with Janssen which resulted in a \$300 million upfront payment and a \$200 million equity investment in January 2019, and (ii) €479.0 million of net proceeds received from the global offering in November 2019.

Operating income increased by €53.4 million for the year ended December 31, 2019 to €82.6 million, compared to €29.2 million for the year ended December 31, 2018. The increase primarily related to (i) the partial recognition of the upfront payment and the recognition of research and development service fees under the collaboration and license agreement for cusatuzumab with Janssen and (ii) the recognition of the milestone payment following the initiation of a first-in-human clinical trial with ABBV-151 under the AbbVie collaboration.

Research and development expenses totaled €197.7 million and €83.6 million for the years ended December 31, 2019 and 2018, respectively. The increase is mainly the result of (i) increased external research and development expenses reflecting higher clinical trial costs and manufacturing expenses related to the development of argenx's product candidate portfolio and (ii) higher personnel expenses as a result of increased costs of the share-based payment compensation plans related to the grant of stock options to its research and development employees and increased costs associated with additional research and development employees.

Selling, general and administrative expenses totaled €64.6 million and €27.5 million for the years ended December 31, 2019 and 2018, respectively. The increase of €37.1 million was principally due to an increase of personnel expense, resulting from (i) higher costs of the share-based payment compensation plans related to the grant of stock options to argenx's selling, general and administrative employees and (ii) increased costs associated with additional employees recruited to strengthen its selling, general and administrative activities, notably in preparation of the potential commercial launch of efgartigimod in the U.S.

For the year ended December 31, 2019, financial income amounted to €14.4 million compared to €3.7 million for the year ended December 31, 2018. The increase of €10.7 million primarily related to an increase in the interest received on argenx's cash, cash equivalents and current financial assets.

Exchange gains totaled €6.1 million for the year ended December 31, 2019 compared to €12.3 million for the year ended December 31, 2018 and were mainly attributable to unrealized exchange rate gains on argenx's cash, cash equivalents and current financial assets position in U.S. dollars due to the favorable fluctuation of the EUR/USD exchange rate.

The total comprehensive loss for the year ended December 31, 2019 was €163.0 million compared to €66.6 million for the year ended December 31, 2018.

US SEC and statutory Financial Reporting

argenx's primary accounting standard for quarterly earnings releases and annual reports is International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB). Quarterly summarized statements of profit and loss based on IFRS as issued by the IASB are available on www.argenx.com.

In addition to reporting financial figures in accordance with IFRS as issued by the IASB, argenx also reports financial figures in accordance with IFRS as adopted by the EU for statutory purposes. The consolidated statement of financial position, the consolidated statements of profit and loss, the consolidated statements of cashflow, and the consolidated statement of changes in equity are not affected by any differences between IFRS as issued by the IASB and IFRS as adopted by the EU.

The consolidated statement of profit and loss data of argenx SE as of December 31, 2019, as presented in this press release is unaudited.

Annual Report 2019

argenx will publish its 2019 Annual Report based on IFRS as issued by the IASB and its 2019 Annual Report for statutory purposes based on IFRS as adopted by the EU on March 24, 2020. These Annual Reports will be available on www.argenx.com.

EXPECTED 2020 FINANCIAL CALENDAR:

- ┆ May 14 2020: Q1 financial results & business update
- ┆ July 30 2020: HY 2020 financial results & business update
- ┆ October 22 2020: Q3 financial results & business update

CONFERENCE CALL DETAILS

The full year results will be discussed during a conference call and webcast presentation today at 3 pm CET/9 am ET. To participate in the conference call, please select your phone number below and use the confirmation code 2484158. The webcast may be accessed on the homepage of the argenx website at www.argenx.com or by clicking [here](#).

Dial-in numbers:

Please dial in 5–10 minutes prior to 3 pm CET/ 9 am ET using the number and conference ID below.

Confirmation Code: 2484158

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About argenx

argenx is a global immunology company developing antibody-based medicines for patients suffering from severe autoimmune diseases and cancer. By translating immunology breakthroughs into innovative drug candidates, argenx is building a world-class portfolio of first-in-class antibodies in both early and late clinical-stages of development. argenx is evaluating efgartigimod in multiple serious autoimmune indications and cusatuzumab in hematological malignancies in collaboration with Janssen, along with advancing earlier stage assets within its therapeutic franchises.

www.argenx.com

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Forward-looking Statements

The contents of this announcement include statements that are, or may be deemed to be, "forward-looking statements." These forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "intends," "may," "will," or "should" and include statements argenx makes concerning its 2020 business and financial calendar and related plans; the clinical data of its product candidates; the intended results of its strategy and argenx's, and its collaboration partners', advancement of, and anticipated clinical development, data readouts and regulatory milestones and plans, including the timing of planned clinical trials and expected data readouts. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. argenx's actual results may differ materially from those predicted by the forward-looking statements as a result of various important factors, including argenx's expectations regarding its the inherent uncertainties associated with competitive developments, preclinical and clinical trial and product development activities and regulatory approval requirements; argenx's reliance on collaborations with third parties; estimating the commercial potential of argenx's product candidates; argenx's ability to obtain and maintain protection of intellectual property for its technologies and drugs; argenx's limited operating history; and argenx's ability to obtain additional funding for operations and to complete the development and commercialization of its product candidates. A further list and description of these risks, uncertainties and other risks can be found in argenx's U.S. Securities and Exchange Commission (SEC) filings and reports, including in argenx's most recent annual report on Form 20-F filed with the SEC as well as subsequent filings and reports filed by argenx with the SEC. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. argenx undertakes no obligation to publicly update or revise the information in this press release, including any forward-looking statements, except as may be required by law.

Attachment

┆ [Y2019 Consolidated Financial Statements argenx SE](#)